REMARKS

The Office action mailed 23 January 2006, has been received and its contents carefully noted. The pending claims, claims 4, 11, 12, 22-25, 29, 30 and 32, were rejected. Reconsideration is respectfully requested.

Rejection under 35 U.S.C. 112, first paragraph

The Examiner rejected the claims under 35 U.S.C. 112, first paragraph, as lacking written description for compositions "free of dextran" and the functional limitation. The Examiner recommended pointing to the Specification by page and line number where conception by way of written description may be found.

Applicants respectfully point to Example 3 in the Specification on pages 16-17, paragraphs 62-63, as providing the written description support for the conception of compositions "free of dextran" and the functional limitation. In particular, lines 2-3 of paragraph 62 explains that a preparation containing dextran was tested. Lines 7-10 of paragraph 62 indicate that one subject developed transient urticaria at the control-diluent site which is consistent with type I hypersensitivity to the dextan and diluent control. The transient urticaria is clearly a false positive result as the control-diluent containing dextran did not contain any microfluidized lysate or any other antigen which could have created an induration at the control site. Paragraph 63 then indicates that the formulation was reformulated as a result of the dextran causing hypersensitivity. Paragraph 71 on page 19 then sets forth an exemplary protocol for testing a control preparation which is a 1:100 dilution of the microfluidized lysate preparation wherein the diluent comprises Tween-80, glycerol, phenol and saline. Notably, dextran is not listed as one of the ingredients in the diluent. Therefore, Applicants respectfully submit that the Specification, in particular Examples 3 and 4 provide written description support for compositions "free of dextran".

Applicants respectfully point out that the "false positive hypersensitivity reaction" of claim 1 refers to the hypersensitivity to dextran as experienced by the subject described in Example 3. Since the composition does not contain dextran, the composition will not result in any reaction, including a hypersensitivity reaction to dextran, which would be a false positive reaction. Therefore, the specification provides written description support for the functional

limitation. Since the limitation is a functional limitation resulting from the absence of dextran, and therefore an inherent characteristic of the claimed preparation, Applicants are amenable to canceling the explicit recitation of the limitation if the Examiner believes doing such would advance prosecution.

Since the Specification provides written description support for preparations "free of dextran" and the functional limitation, the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn as well as the objection to the Specification.

Rejection under 35 U.S.C. 102(b)

The Examiner rejected the claims under 35 U.S.C. 102(b) as being anticipated by Leishmania Research Project DoD-8B or Stiteler et al. (1994, 1995, 1998). Specifically, the Examiner pointed to the last line of Rowton et al. (1996) for indicating that the preparations do not cause a false positive hypersensitivity reaction.

Applicants respectfully submit that the Examiner takes the last line of Rowton et al. (1996) out of context. In particular, the last line reads:

There were no responses at any dose level in naïve guinea pigs.

Applicants point out that Rowton et al. (1996) is unclear as to what *preparation* was tested that did not provide any reaction. It is also unclear as to what *reaction* was not observed. Specifically, Rowton et al. (1996) refers to an Arthus reaction and delayed type hypersensitivity (DTH reactions) and testing MFL-LSTA and controls. The last line of Rowton et al. (1996) could mean that there were no Arthus reactions to control preparations, there were no Arthus reactions to control antigens, there were no Arthus reactions to the MFL-LSTA preparation, there were no DTH reactions to control preparations, there were no DTH reactions to control antigens, or there were no DTH reactions to the MFL-LSTA preparation. Further, Applicants respectfully submit that Rowton et al. (1996) indicates the testing was done in guinea pigs, not human subjects. Although animal models are generally acceptable for being indicative of bioactivity and toxicity in humans, it is well known in the art that animals and humans exhibit different hypersensitivities to a plurality of compounds.

The Examiner stated that "the function of not causing false positives is an inherent property of the microfluidized product of the prior art". Applicants respectfully submit that

Example 3 of the Specification proves this statement is incorrect. In particular, a prior art microfluidized preparation was tested and did, in fact, cause a false positive reaction. Thus, it cannot be said that prior art microfluidized lysate preparations do not cause false positive reactions, when they actually do.

In order to anticipate, a reference must teach each and every element of the claimed invention. Nowhere do the cited prior art teach microfluidized lysate preparations which are (1) free of dextran and (2) do not cause a false positive result. Since it is unclear as to what preparation was tested and what reaction did not result in Rowton et al. (1996), Rowton et al. (1996) can not be interpreted as teaching microfluidized lysate preparations which do not cause a false positive result and are therefore free of dextran.

Nowhere do the disclosures of Leishmania Research Project DoD-8B or Stiteler et al. (1994, 1995, 1998), teach microfluidized lysate preparations which are (1) free of dextran and (2) do not cause a false positive result or that the preparations tested were the same as the unknown preparation of Rowton et al. (1996) which did not provide an unknown response. Therefore, none of the cited prior art teach each and every limitation of the claimed invention.

Further, Applicants reiterate that the cited references are non-enabling references. The prior art does not enable microfluidized lysate preparations that do not cause false positive hypersensitivity reactions. Specifically, the prior art does not teach or suggest which ingredients in the lysate preparations might be responsible for causing false positive hypersensitivity reactions. In order to be enabling, the prior art would have to teach or suggest that dextran was the ingredient that caused false positive hypersensitivity reactions. Nowhere do the cited prior art teach or suggest that dextran was the ingredient in the microfluidized lysate preparations that caused false positive hypersensitivity reactions. Consequently, the cited prior art is nonenabling and as a result can not anticipate the claimed invention.

Therefore, Applicants respectfully assert that the claims as amended are novel and the rejection under 35 U.S.C. 102(b) should properly be withdrawn.

Rejection under 35 U.S.C. 103(a)

The Examiner rejected the claims under 35 U.S.C. 103(a) as being unpatentable over Leishmania Research Project DoD-8B or Stiteler et al. (1994, 1995, 1998) and further in view of

Reed et al.

As set forth above, none of the cited prior art references teach microfluidized lysate preparations which are (1) free of dextran and (2) do not cause a false positive result.

No combination of the cited references result in a microfluidized lysate preparation which is (1) free of dextran and (2) does not cause a false positive result. Thus, a prima facie case of obviousness can not be established. Further, since it is unclear as to what preparation was tested and what reaction did not result in Rowton et al. (1996) one skilled in the art would not have been motivated combine the cited references to obtain a microfluidized lystate preparation (1) free of dextran which (2) does not result in a false positive hypersensitivity reaction with a reasonable likelihood of success.

Therefore, the claimed invention is unobvious and the rejection under 35 U.S.C. 103(a) should properly be withdrawn.

Request for Interview

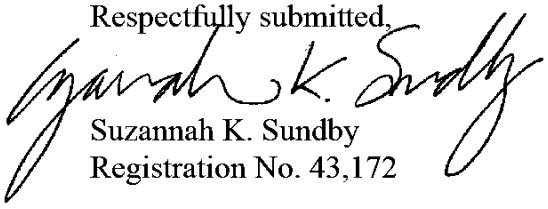
Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 210-380,** Attorney Docket No. **034047.013 (WRAIR 98-40/46)**.

Respectfully submitted,



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